IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS INC. and ABBOT LABORATORIES INC.,	)	Civil Action No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR))
Plaintiffs,	)	
v.	)	
MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,	)	
Defendants.	)	

DECLARATION OF JOEL K. KAHN, M.D.

I, Joel K. Kahn, hereby declare as follows:

1. I am a medical doctor specializing in interventional cardiology. I am a certified specialist in internal medicine and a certified sub-specialist in cardiovascular medicine and interventional cardiology. After graduating summa cum laude from the University of Michigan Medical School in 1983, I was an internal medicine resident for three years at University Hospital in Ann Arbor, Michigan. I was then a cardiology fellow for three years at University of Texas Southwestern Medical Center and an advanced angioplasty fellow for one year at the Mid-America Heart Institute of St. Luke's Hospital, Kansas City, Missouri. My *curriculum vitae* is attached as Exhibit 1.

2. I currently perform approximately 400 invasive procedures per year, including 150-200 percutaneous coronary interventions ("PCI") per year. Another commonly used term for PCI is percutaneous transluminal coronary angioplasty ("PTCA") or "balloon angioplasty." Since 1986, I have performed approximately 5,000 PCI procedures. I have personally implanted

a number of different stents in human patients, including the Multi-Link family of stents and various stents sold by Medtronic.

3. I currently serve on the editorial board of the Journal of Interventional Cardiology. I previously served on the editorial board of Catheterization and Cardiovascular Intervention. In addition, I review and judge original research and peer reviewed articles submitted for publication in other medical journals on an *ad hoc* basis.

4. I have been retained in this matter by Advanced Cardiovascular Systems, Inc. ("ACS") as an expert on the clinical use of coronary and peripheral stents. I am being compensated at $500 per hour for my time. I have been retained and compensated by ACS in other litigation matters, and testified at the trial in this case in February 2005.

5. I have been asked to opine on whether a court order precluding the sale in the U.S. of certain Medtronic stents, including the Microstent II, GFX, GFX 2, GFX 2.5, S540, S660, S670, S7, BeStent 2, Driver, MicroDriver, and Racer, would have any significant negative impact on patients suffering from coronary artery disease and other diseases typically treated with a stent. I have also been asked to opine on whether a court order that precluded Medtronic from introducing its Endeavor stent into the United States would have any significant negative impact on patients that could be treated with a drug-eluting stent ("DES").

6. In my practice as an interventional cardiologist, I have used many of the Medtronic stents listed in ¶ 5 above. Most recently, of those stents, I have primarily been using the Driver and MicroDriver stents. Both of these products are bare-metal (non-DES) stents used for the treatment of coronary artery disease.

7. I am also familiar with many (if not all) of the competing bare-metal stents on the U.S. market, such as stents sold by ACS, Boston Scientific, and Cordis. Based on the variety of

these competing stents, if Medtronic were to stop selling its stents in the United States, I would still have a sufficient selection of sizes and varieties of stents necessary to perform all desired procedures. Based on my personal experience, my review of medical literature, and my discussions with colleagues, moreover, Medtronic's stents are no safer or more effective than other stents on the market, such as those made by ACS, Boston Scientific, and Cordis. Accordingly, based on the variety of competing stents currently available, neither physicians nor patients will be harmed if Medtronic's infringing stents are taken off the market.

8. In my practice, I also use DES products, including Boston Scientific's Taxus stent and Cordis's Cypher stent.

9. I understand that Medtronic has released a DES product, known as the "Endeavor," outside of the United States, and that it anticipates releasing the Endeavor in the U.S. this year. I understand that the Endeavor uses Medtronic's Driver stent as its platform.

10. Based on my review of medical literature concerning the Endeavor and my experience with the Driver stent, I do not believe that the Endeavor would provide any significant additional medical benefit over the DES products currently on the market (i.e., Taxus and Cypher).

11. In an article published in December 2006, physicians performing clinical evaluations of the Endeavor described it as having "significantly higher angiographic late lumen loss" (i.e., restenosis) than Cordis's Cypher stent. Ex. 2 at 2447 [Kandzari et al, "Comparison of Zotarolimus-Eluting and Sirolimus-Eluting Stents in Patients With Native Coronary Artery Disease," Circulation, Vol. 48, No. 12, Dec. 19, 2006]. This article also stated that "most other angiographic outcomes favored" the Cypher stent over the Endeavor stent. *Id.* Based on my

review of this article, the Endeavor may be somewhat inferior to, or at least no better than, the Cypher stent.

12. Another article, dated April 4, 2007, described the Endeavor stent as "equivalent to the sirolimus-eluting Cypher stent, in terms of clinical end points," and stated that "target lesion revascularization (TLR) at two years were not statistically different for the two drug-eluting stents (DES), although fewer patients randomized to the Endeavor experienced periprocedural non-Q-wave MI, a difference that was maintained over the two years of follow-up." Ex. 3 [Wood, "Two-year results from ENDEAVOR III point to safety, efficacy," the heart.org, April 4, 2007]. While this article notes that the Endeavor study showed slightly lower rates of myocardial infarction compared to the Cypher, it also states that this is "a difference that might have been explained by the manner in which events were measured in the trial." *Id.* Additionally, as to this issue, the article noted that the study size was "relatively small" and that "sometimes you see statistical significance not biologically meaningful, but just due to the large confidence intervals of a small sample size." *Id.* This article also stated that "numerically TLRs [i.e., restenosis] were greater in the Endeavor stent-treated patients, while deaths were numerically lower." *Id.* On the subject of myocardial infarction rates between Endeavor and Cypher, however, the clinical results described in this article were inconclusive.

13. According to the April 4 article, Dr. Martin Leon, who presented the two-year results of the Endeavor III trial at the American College of Cardiology 2007 Scientific Sessions, explained that "the two-year results from Endeavor III alone do not add much to the stent-thrombosis debate, since rates of stent thrombosis per the trial's definition were zero between both stents" (i.e., Endeavor and Cypher). *Id.* Dr. Leon also stated that "there have been no reported stent thromboses" with the Endeavor, and that "we're beginning to achieve a large-

enough sample size where our confidence about late stent thrombosis is increasing," but that "[i]t's by no means definitive: I'm anxious to see three-year follow-up from Endeavor II and whether these results continue to sustain themselves." *Id.*

14. Based on my review of the April 4 article, the data on late-stent thrombosis for the Endeavor is inconclusive. While Medtronic's Endeavor has not yet resulted in any reported cases of late-stent thrombosis, as Dr. Leon acknowledges, the results to date are "by no means definitive," and we must wait for further results before drawing any conclusions on late-stent-thrombosis rates in the Endeavor.

15. I have not seen anything in the medical literature that suggests that the Endeavor would provide any significant additional medical benefit over the Cypher and Taxus stents, which are currently available in the United States. If anything, the literature suggests that the Endeavor may have a higher rate of restenosis, which is not desirable. As mentioned above, the study results comparing the rates of myocardial infarction and late-stent thrombosis between the Endeavor and the Cypher were inconclusive and thus not helpful.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code. Executed on this the 29th day of June, 2007.

Joel Kahn, MD

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DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on June 29, 2007, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on June 29, 2007, I have sent by Federal Express the foregoing document to the following non-registered participants:

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